REMARKS/ARGUMENTS

Amendment to the Claims

Claims 1-15 are currently in the application. Claims 3, 6-9 and 11 are amended. Claims 12-15 are withdrawn from consideration. New Claims 16 and 17 are added.

Claim 3 is amended to correct grammar. Claims 6, 7, 8 and 11 are amended to correct antecedent basis to "at least one engaging member". Claim 8 is also amended to delete the "preferably" phrase. Claims 8 and 9 are also amended to change dependency.

New claim 16 is made dependent to Claim 1 and provides that the device is configured to hold itself in a position attached to the skin of the patient, without requiring a medical technician, the patient, or other person, to hold the device, during the time that the vaccine is injected into the patient through the needle, and wherein the adhesive on the skin-facing surface of the separable base provides adhesive, hands-free, self-attachment of the device to the skin of the patient. Support is found at paragraphs [0056] and [0061].

New claim 17 depends from Claim 1 and further comprises a means for injecting the vaccine at a substantially constant volumetric flow rate of about 0.5 μL/s to about 20 μL/s. Support is found at paragraph [0060].

No new claims fees are believed due, and all claim amendments are fully supported by the specification as originally filed.

Claim Objections

Claim 3, 6, 8 and 11 were objected to for grammar, and lack of antecedent basis for terms.

Applicants request reconsideration and withdrawal of the objections in view of the claim amendments.

Rejections under 35 USC §103(a)

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over McConnell-Montalvo (US 5527287) in view of Woehr et al. (US 20030144627) and Hunn et al (US 20040158207).

Applicants traverse.

Rejections based on 35 U.S.C. § 103 must rest on a factual basis. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. Obviousness is a question of law based on underlying factual inquiries. The factual inquiries include:

(A) determine the scope and contents of the prior art; and

(B) ascertaining the differences between the claimed invention and the prior art.

a. The rejection fails because the Examiner's factual characterization of the prior art is incorrect.

In the present case, the Examiner's characterization of the prior art is factually incorrect, and on that basis alone, the rejection fails to state the *prima facie* obviousness requirement.

At the outset, the Examiner's finding that McConnell-Montalvo discloses a device for self-administered injections, is *factually incorrect*. The term "self-administering" is defined in the specification at paragraph [0056] as the device holding itself in a position attached to the skin of the patient, without requiring a medical technician, the patient, or other person, to hold the device, during the time that an injectable liquid composition contained within the device is injected into the patient through the injection needle. While the pending claims must be "given their broadest reasonable interpretation", that interpretation must be "consistent with the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005).

The device described in McConnell-Montalvo is held in position and activated by hand, either the hand of the patient for "self-injection" or "self-performed" injections, or by another person. There is no description or suggestion, and no motivation provided by McConnell-Montalvo, to use the device as, or to modify the device into, a "self-administering" device, as provided by Applicants' claims. And to construe Applicants' claims as such is inconsistent with the specification.

Furthermore, the Examiner's finding that McConnell-Montalvo discloses a device for painless injections is *factually incorrect*. McConnell-Montalvo mentions that "rapid placement

of a needle hypodermically is perceived to be less painful", and that "substantial pressure ... exerted around the injection site by the housing... can give the perception that there is less pain." However, McConnell-Montalvo makes no statement that its device either inserts the needle painlessly, or causes the injectable vaccine to flow into the patient painlessly." In fact, a person of ordinary skill would understand that "perception" is not reality, and would predict that the needle insertion and vaccine injection of the device of McConnell-Montalvo is nonetheless painful.

Still further, the Examiner's finding that McConnell-Montalvo discloses a device with a separable base is *factually incorrect*. McConnell-Montalvo discloses an injection housing with "a latch... slidably mounted within the end section 76 of the housing 70." (Fig. 8 and col 5 lines 59-60). What the Examiner states on the record to be "separable", is a latch that is slidable along, but is not separable from, the housing.

In addition, Claim 2 provides that the separable base can be reaffixed to the base portion. The rejection states (page 5 first line of the Action) that this moveable latch can be "reaffixed" to the base at the top of the space 100). Where does the reference state this? At best, the slot 100 can retain the moveable latch in one position, which neither makes the latch separable from the housing, nor retained to the skin of the patient after separation, as clearly described in Applicants' specification.

Woehr et al disclose a list of the international standards for push and pull strengths that a needle and hub must provide based on a needle's outer diameter (Table 1). The needle sizes described in Table 1 do not inherently provide for painless needle insertion into the skin across the full range of sizes. A few of the sizes may, but most do not. For the record, Woehr et al teaches a unique hypodermic needle assembly having a needle shield that can be retracted from blocking the hypodermic needle tip. Woehr et al do not describe expressly the use of any particular needle size, and provide no teaching or suggestion of the problem of pain caused by the use of larger-diameter sized needles during intramuscular needle insertion. Consequently, while it may be possible that the device of McConnell-Montalvo could be modified by using one of the needles of any size shown in the Table 1 of Woehr et al, such mere possibility does not make the modification obvious unless the prior art suggested the desirability of the modification

(see In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). Neither McConnell-Montalvo nor Woehr et al recognize, discuss or would suggest the benefit of a painless needle insertion, involving the appropriately sized needle defined by Applicants. And the addition of Hunn et al does not help or correct this deficiency.

b. The rejection fails to provide a rational basis to combine the teachings of the references.

"'Rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

The rejection states that it would be obvious to modify McConnell-Montalvo with the smaller-diameter needles of Woehr et al "for the purpose of providing a needle of sufficiently sized diameter to require an appropriate application of strength for use". The Push and Pull strengths in Table 1 of Woehr et al describe the international standards for the minimum strength from physical separation of a needle from its hub. The rationale provided by the Examiner, as motivation for combining the McConnell-Montalvo and Woehr et al references, cannot be understood. What does the Examiner mean? Without an articulated, rationale basis, the mere conclusion that it would be obvious to combine a selected feature in Woehr et al into the device of McConnell-Montalvo is, standing alone, not sufficient to establish a *prima facie* case of obviousness. [Some objective reason to combine the teachings of the references is required. "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art, is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references." *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).]

The rejection continues by stating that it would be obvious to modify McConnell-Montalvo such that it comprises an adhesive on a skin-facing surface thereof, an adhesive flap extending from a periphery of the separable base, the flap having an adhesive on a skin-facing surface thereof, whereby the flap provides securement of the separable base to the skin of the

patient, as allegedly taught by Hunn et al, for holding the apparatus in place at an injection site.

The device of McConnell-Montalvo makes no disclosure or suggestion that the device is to be attached to the skin, and would be understood by a person of ordinary skill to provide that the device is held by hand against the skin for only so long as it takes the user to insert the needle and plunge the contends of the reservoir through the needle.

Furthermore, the device described in Hunn et al is an infusion set. Infusion and injection are quite different methods. A person of ordinary skill in the art would see that Hunn et al use the needle 8 as an insertion means for the infusion tube 3, and that a separate plug 9 of the liquid supply device (Fig. 1) is affixed to the base and body 1,2 for infusion of the liquid. The Examiner has not provided a rationale basis or any objective reason to combine the teachings of the references as required. The actual teaching of Hunn et al uncuts and refutes the rationale offered in the rejection.

c. The rejection employs hindsight to select isolated features from the teachings of the references.

To a person of ordinary skill in the art, Woehr et al teach a unique hypodermic needle assembly having a needle shield that can be retracted from blocking the hypodermic needle tip. The Examiner has inappropriately taken just one feature (the Push and Pull strength values for a broad range of needle sizes) from the teaching of an otherwise unique needle assembly, and attempts to modify McConnell-Montalvo with that single feature only. The well established rule of law is that each prior art reference must be evaluated as an entirety, and that all of the prior art must be evaluated as a whole. See W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d at 1550, 220 USPQ at 311; In re Kuderna, 426 F.2d 385, 390, 165 USPQ 575, 578-79 (CCPA 1970). The Examiner cannot select isolated features from the prior art to combine, without some motivation provided by the references. The only motivation in the record for a person of ordinary skill to select the isolated feature (needle size) from Woehr et al to combine with McConnell-Montalvo is applicants' invention, which amounts to impermissible hindsight.

Furthermore, if a person of ordinary skill were to attempt to combine the unique hypodermic needle assembly of Woehr et al, with the device of McConnell-Montalvo, the resulting product design and function would be unpredictable, and not obviously functional. Just how would one configure and activate the needle guard assembly 16 and the spring clip 20 prior

to extending out to the tip of the needle? It is not immediately obvious.

Finally, it is clearly insufficient for the Examiner, in formulating a rejection, to merely take Applicants' claim scope, insert it into the rejection, and then attribute that scope to any one of the references. The rejection makes no attempt to describe what the references teach, or to explain how such reference teaching is construed as that of Applicants' claim elements and features. This is in fact, hindsight *per se*, since Applicants' claims are literally pasted into the rejection to serve as the scope attributed to the different references.

Applicants new claim 17

Finally, in terms of Applicants' new claim 17, which provides for specific liquid flow rates to effect a painless injection of the injectable liquid, neither McConnell-Montalvo nor Woehr et al recognize, discuss or would suggest the benefit of a painless intramuscular injection, involving the appropriately-configured injection means for constant volumetric delivery of the liquid painlessly.

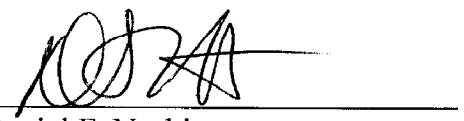
For that matter, none of the prior art of record discloses the problem of pain associated with intramuscular vaccines and liquid injections, and the means for both a painless needle insertion into the muscle and a painless injection of the vaccine.

Conclusion

Applicant believes a complete response to the office action has been provided, and that the present invention as claimed clearly distinguishes the teachings of the prior art of record. Applicant requests a prompt allowance of all claims.

Respectfully submitted,

For: Eric James WALL et al.

By: 

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